DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 25,2014

Ivoclar Vivadent, Inc.
Donna Marie Hartnett
Director QA/Regulatory Affairs
175 Pineview Drive
Amherst, New York 14228

Re: K142389
Trade/Device Name: Variolink® Esthetic
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: II
Product Code: EBF
Dated: August 8, 2014
Received: August 27, 2014

Dear Ms. Hartnett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K142389

Device Name: Variolink® Esthetic

Indications For Use:

Variolink Esthetic LC:

– Permanent adhesive luting of glass-ceramic, lithium disilicate glass-ceramic and composite restorations (inlays, onlays and veneers)

- Only use Variolink Esthetic LC for restorations with a low thickness of <2mm that have sufficient translucency (e.g. restorations made of IPS e.max R HT).

Variolink Esthetic DC:
– Adhesive luting of glass-ceramic, lithium disilicate glass-ceramic and composite restorations (inlays, onlays,partial crowns, crowns, bridges).

– Restorations made of opaque ceramics, e.g. oxide ceramics, can only be permanently cemented if an adhesive is additionally used that is separately light-cured.

Variolink Esthetic Try-In

To evaluate the overall effect of the restoration in conjunction with the various Variolink Esthetic shades prior to permanent cementation.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(K) SUMMARY
Variolink Esthetic

Contact: Donna Marie Hartnett

Company: Ivoclar Vivadent, AG
Bendererstrasse 2, Schaan, FL-9494, Liechtenstein
+423-235-3535

Date Prepared: November 25, 2014

Proprietary Name: **Variolink® Esthetic**

Classification Name: Material, Tooth Shade, Resin (872.3690)
(Classification Code EBF)

Predicate Device: Variolink II (K971372)

Device Description: Variolink® Esthetic is a color-stable adhesive luting system for the permanent cementation of ceramic and composite resin restorations. Variolin Esthet6ic is offered in a purely light-curing (LC) and dual-curing (DC) version. Try-In pastes are also included for shade matching purposes. The materials are offered in five shade gradations (Light+, Light, Neutral, Warm and Warm+)

Intended Use:
Variolink Esthetic LC:

– Permanent adhesive luting of glass-ceramic, lithium disilicate glass-ceramic and composite restorations (inlays, onlays and veneers)

- Only use Variolink Esthetic LC for restorations with a low thickness of <2mm that have sufficient translucency (e.g. restorations made of IPS e.max R HT).

Variolink Esthetic DC:
– Adhesive luting of glass-ceramic, lithium disilicate glass-ceramic and composite restorations (inlays, onlays,partial crowns, crowns, bridges).

– Restorations made of opaque ceramics, e.g. oxide ceramics, can only be permanently cemented if an adhesive is additionally used that is separately light-cured.

Variolink Esthetic Try-In

To evaluate the overall effect of the restoration in conjunction with the various Variolink Esthetic shades prior to permanent cementation.

510(K) SUMMARY
Variolink Esthetic

Comparison to Predicate: The predicate device to which Variolink® Esthetic has been compared is Variolink II (K971372). For this application, Variolink® Esthetic has been compared to its predicate with regard to chemical composition, physical properties, and indications for use. The comparison shows that Variolink® Esthetic is substantially equivalent to the predicate device.

Predicate - Variolink II K971372	Subject Device
Variolink II is a dual-curing (light- and self-curing) luting composite system for the adhesive luting of ceramic and composite restorations. Variolink II may also be applied in the light-curing technique only (e.g. luting of veneers). For this purpose, only the Variolink II Base is to be used. Variolink II Try-in Pastes. Water-soluble glycerine pastes shades to match the cement and used temporarily before cementation to visualize the final shade.	Variolink Esthetic is a color-stable, adhesive luting system for the permanent cementation of ceramic and composite resin restorations. Variolink Esthetic is offered in a light-curing version (Variolink Esthetic LC) and a dual-curing version (Variolink Esthetic DC). Variolink Esthetic also includes an accessory product, Variolink Esthetic Try-in which are water-soluble glycerine pastes shaded to match the Variolink Esthetic cement and used temporarily before cementation to visualize the final shade.
Variolink II is available in 6 base shades and 2 catalyst shades. The catalyst is available in different viscosities. Variolink II is available in syringes. Base and catalyst are hand-mixed.	Variolink Esthetic is available in 5 shades: Light +, Light, Neutral, Warm, Warm + Variolink Esthetic DC is available in one consistency. Variolink Esthetic LC is available in syringes. Variolink Esthetic DC is available in double-push syringes with mixing tips so the material is dispensed ready-mixed.
Cool storage (2–8 °C/36–46 °F) is indicated for the catalyst paste. Syringes should be closed immediately after use. Exposure to light causes premature polymerization.	2-28 °C/36-82 °F for all items. Close Variolink Eshetic LC syringes immediately after use. Exposure to light causes premature polymerization.

Technological Characteristics and Testing Summary: The device has been tested and designed in accordance with ISO 4049:2009 Dentistry - Polymer-based restorative materials for film thickness, Depth of Cure, sensitivity to ambient light, working time, setting time, flexural strength, water sorption, solubility, and radiopacity. Biocompatibility testing has been assessed according EN ISO 10993-1:2009 and EN ISO 7405:2008. The device design, i.e. delivery form, and intended use of Variolink® Esthetic and the predicate device are the same.

510(K) SUMMARY
Variolink Esthetic

Guidance Document: This submission complies with the requirement of "Guidance for Industry and FDA Staff: Dental Composite Resin Devices - Premarket Notification [510(k)] Submissions" dated October 26, 2005.

CONCLUSION: The above data and analysis demonstrates that Variolink® Esthetic is substantially equivalent to the predicate device.